

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****[Docket No. 99N-1075]****Public Health Impact of *Vibrio Parahaemolyticus* in Molluscan Shellfish****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice of public meeting.

**SUMMARY:** The Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition, in conjunction with the Risk Assessment Advisory Committee on Microbiological Criteria for Foods, in cooperation with the Food Safety and Inspection Service, U.S. Department of Agriculture (FSIS/USDA) is announcing a public meeting to discuss issues related to risk assessment models being developed to examine the relationship between *Vibrio parahaemolyticus* and human health.

**DATE:** The public meeting will be held on Wednesday, May 26, 1999, from 8 a.m. to 5 p.m. Submit written notices of participation by May 20, 1999. Written comments will be accepted until June 30, 1999.

**ADDRESSES:** The public meeting will be held at the Ambassador West Hotel, 1300 North State Parkway, Chicago, IL. Submit registration and written notices of participation to Catherine M. DeRoever (address below). Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

Catherine M. DeRoever, Executive Operations Staff (HFS-22), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St., SW., Washington, DC 20204, 202-205-4251, FAX 202-205-4970, or e-mail "cderoeve@bangate.fda.gov".

Those persons interested in attending the public meeting should, by May 20, 1999, fax their name, title, firm name, address, and telephone number to Catherine M. DeRoever (fax number above).

Those persons interested in presenting information at the meeting should, by May 20, 1999, fax their name, title, firm name, address, telephone number, and an outline of

their presentation to Catherine M. DeRoever (fax number above).

There is no registration fee for this public meeting, but advance registration is suggested. Interested persons are encouraged to register early because space may be limited.

**SUPPLEMENTARY INFORMATION:** This public meeting will provide an opportunity for an open discussion of the issues related to risk assessment models under development that will be used to examine the relationship between *V. parahaemolyticus* and human health.

The agenda will include presentations on such topics as: (1) Introduction to the risk assessment, (2) preharvest and harvest, (3) postharvest, (4) epidemiology of *V. parahaemolyticus* outbreaks, (5) consumption patterns, and (6) characteristics of *V. parahaemolyticus* dose-response.

The sponsoring agencies encourage individuals with relevant scientific data or information, i.e., information concerning preharvesting, harvesting and postharvesting, epidemiology, exposure, and dose-response relationship of *V. parahaemolyticus*, to present such information at the meeting or in written comments to this record.

A transcript of the public meeting will be prepared. Copies of the transcript may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting. The transcript of the public meeting and submitted comments will be available for public examination at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 29, 1999.

**William K. Hubbard,**

*Acting Deputy Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****[Docket No. 99N-1075]****Risk Assessment on the Potential Public Health Impact of *Vibrio Parahaemolyticus* in Molluscan Shellfish; Request for Scientific Data and Information****AGENCY:** Food and Drug Administration, HHS.**ACTION:** Notice; request for scientific data and information.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a call for scientific data and information relevant to the agency's planned risk assessment on the potential public health impact of pathogenic *Vibrio parahaemolyticus* infections resulting from the consumption of raw molluscan shellfish. The risk assessment will assist FDA by providing a scientific framework for developing food safety policies relating to raw molluscan shellfish contaminated with pathogenic *V. parahaemolyticus*. FDA plans to hold public meetings to present the process of the risk assessment, to present information collected, and to allow interested parties additional opportunities to present data to facilitate this effort.

**DATES:** Submit scientific data and information by July 6, 1999.

**ADDRESSES:** Submit scientific data and information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:**

Marianna D. Miliotis, Center for Food Safety and Applied Nutrition (HFS-327), Food and Drug Administration, 200 C St., SW., rm. 3472, Washington, DC 20204, 202-205-4824, FAX 202-205-4939, or e-mail "mmilioti@bangate.fda.gov."

**SUPPLEMENTARY INFORMATION:****I. Background****A. *Vibrio parahaemolyticus***

*V. parahaemolyticus* is a gram-negative, halophilic bacterium that occurs naturally in estuarine environments and, therefore, can be present in many fishery products, including molluscan shellfish (Ref. 1). The organism can cause acute gastroenteritis in consumers (Refs. 2, 3, and 4), and in some individuals can also cause septicemia (Ref. 5) and even death (Ref. 6), though such cases have been reported only rarely. Worldwide, this organism is one of the leading causes of foodborne illnesses (Ref. 7). In the United States, the outbreaks caused by this organism usually have been associated with cooked crabs (Ref. 8), and illnesses transmitted by raw molluscan shellfish generally have been limited to sporadic cases (Ref. 9). However, in 1997 *V. parahaemolyticus* from molluscan shellfish caused a large outbreak of illness involving a total of 209 individuals in the Pacific Northwest region, from California to British Columbia (Ref. 10). Many of these cases implicated oysters from specific growing areas, and the magnitude of this outbreak was considerably larger than